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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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EXAMINER	
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1812	12

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 8/18/97.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 21-41 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) 21-30, 34-41 is/are allowed.

☒ Claim(s) 31-33 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☒ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

1. Claims 21-41 are pending in the instant application.

2. The request by the Patent Office to cancel new matter from the specification is withdrawn in view of the Deposit receipt and attorney's statement on page 6 of the response.

The rejection of claims 37 and 39 under § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, is withdrawn.

The rejection of claims 21, 22, 23, 30-33, 37, 38, and 41 under § 112, second paragraph, is withdrawn.

3. It is suggested that claims 21 and 37, line 2 be amended by deleting "a" before "95%."

It is suggested that claims 22 and 23 be amended by inserting a "comma" after "claim 21."

4. The rejection of claims 21-30 and 34-41 under § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, is withdrawn. These claims are directed to nucleic acids encoding SEQ ID NO: 2 which is the amino acid sequence of a naturally occurring G-protein coupled receptor. Naturally occurring G-protein coupled receptors are routinely used in binding assays to determine whether

specific ligands, that are well known in the art, bind to them. These claims also encompass nucleic acids having at least 95% sequence identity to a polynucleotide encoding a polypeptide having the amino acid as set forth in SEQ ID NO: 2. The specification enables the use of these nucleic acids as hybridization probes. Claim 41 is directed to a method of making a polypeptide but is limited to a polynucleotide comprising nucleotides 93-1712 of SEQ ID NO: 1.

However, the rejection of claims 31-33 under § 112, first paragraph, is maintained for the reasons set forth below.

5. Claims 31-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing a polypeptide comprising expressing the nucleic acid encoding SEQ ID NO: 2 in a host cell, does not reasonably provide enablement for a method of producing a polypeptide comprising expressing in a host cell, a nucleic acid having 95% sequence identity to a polynucleotide encoding a polypeptide having the amino acid sequence as set forth in SEQ ID NO: 2, or comprising expressing a nucleic acid that is complementary to the nucleic acid encoding SEQ ID NO: 2 or to the nucleic acid having 95% sequence identity to the nucleic acid encoding SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims as they stand broadly encompass a method of making a polypeptide comprising expressing a nucleic acid that is complementary to the nucleic acid encoding SEQ ID NO: 2, a

nucleic acid that has 95% sequence identity to a polynucleotide encoding a polyepptide having the amino acid sequence as set forth in SEQ ID NO: 2, or a nucleic acid that is complementary to a nucleic acid having 95% sequence identity to the polynucleotide encoding SEQ ID NO: 2. The claimed method encompasses production of polypeptides that are structurally and functionally distinct from SEQ ID NO: 2. First of all, expression of the complementary nucleic acids in host cells produces polypeptides that are unrelated to SEQ ID NO: 2. It is not predictable that the encoded polypeptide would be a G-protein coupled receptor. In fact, it is not predictable as to what polypeptide would be encoded by the complementary strand of the nucleic acid encoding SEQ ID NO: 2. It is known to the skilled artisan that the complementary strand encodes a polypeptide that is structurally and functionally distinct from the polypeptide encoded by the coding strand. Neither the specification nor the prior art has provided guidance to enable the skilled artisan to use polypeptides encoded by the complementary strand of a G-protein coupled receptor. Accordingly, due to the unpredictable nature of polypeptides encoded by the complementary nucleic acids and the lack of guidance from the specification and the prior art, it would require undue experimentation of the skilled artisan to use polypeptides obtained by expressing the complementary nucleic acids of claim 21 in a host cell, and to practice the invention of claims 31-33.

Secondly, expression of polynucleotides having at least 95% sequence identity with the polynucleotide encoding SEQ ID NO: 1 produces polypeptides that are also structurally and functionally distinct from the polypeptide having SEQ ID NO: 2. It is not predictable as to what

functional properties these polypeptides will possess. In fact, it is not predictable that they can be used as G-protein coupled receptors. The specification discloses that the polypeptide having SEQ ID NO: 2 is a G-protein coupled receptor; however, the specification does not disclose polynucleotides having 95% sequence identity with the nucleic acid encoding SEQ ID NO: 1, encode a G-protein coupled receptor. Neither the prior art nor the specification provides guidance as to nucleic acids that can be altered without affecting the functional activity of the encoded G-protein coupled receptor or nucleic acids that must be retained in order for the encoded protein to have the functional properties of a G-protein coupled receptor. It is not predictable from the primary structure of a G-protein coupled receptor as to what amino acids are required for G-protein coupled receptor functional activity. It is known to the skilled artisan that amino acid alterations affect the functional activity of a protein. Therefore, it is not predictable that a polypeptide encoded by a nucleic acid in which 5% of its nucleotides have been altered, would be a functional G-protein coupled receptor. The G-protein coupled receptor having SEQ ID NO: 2 comprises 541 amino acids and is encoded by a nucleic acid sequence having 1623 nucleotides. The number of possible nucleotide alterations (and amino acid alterations) is enormous. The quantity of experimentation required to make a polypeptide having G-protein coupled receptor activity by expressing its encoding nucleic acid in a host cell is unduly burdensome. Accordingly, due to the unpredictable functional properties of polypeptides encoded by a nucleic acid having 95% sequence identity to a nucleic acid encoding SEQ ID NO: 2 and the lack of working example and guidance from the specification and the prior art for obtaining

functional G-protein coupled receptors by nucleic acid alteration of SEQ ID NO: 1, it would require undue experimentation of the skilled artisan to practice the claimed invention.

6. Applicant's arguments filed August 18, 1997, have been fully considered but they are not persuasive.

First of all, it is pointed out that the claims were indicated as free of the prior art in the Office action of March 13, 1997. The Office action of March 13, 1997, did not state that the claims were allowable. In fact, in that Office action, all the claims were rejected under § 112, first paragraph. Thus, the attorney incorrectly stated on page 8 of the response of August 18, 1997, "Prior to. . .we can note the subject matter indicated as allowable by the Examiner."

Applicant points out that the claimed polynucleotides are enabled by the specification for use as probes and that the polypeptide having SEQ ID NO: 2 are allowable. It is acknowledged that the claims directed to the polynucleotides and to a method of making a polypeptide having SEQ ID NO: 2 are enabled by the specification. The claims that are rejected under § 112, first paragraph, as set forth above, are claims 31-33 which encompass a method of making a polypeptide using nucleic acids complementary to the nucleic acid encoding SEQ ID NO: 2, nucleic acids having 95% sequence identity with the nucleic acid encoding SEQ ID NO: 2, and nucleic acids complementary thereof. Claims that are limited to polynucleotides encoding SEQ ID NO: 2 or having 95% sequence identity with the nucleic acid encoding SEQ ID NO: 2 or

method of making a polypeptide having SEQ ID NO: 2 are not included under the § 112, first paragraph, rejection.

Applicant argues that the polypeptides encoded by the complements, as taught by the specification, are useful for making antibodies for detecting the presence of themselves or in the production of host cells comprising the complementary polynucleotides. However, the specification does not disclose how to use antibodies to produce host cells comprising the complementary polynucleotides. Although antibodies against SEQ ID NO: 2 can be used to detect the polypeptide having SEQ ID NO: 2, antibodies against SEQ ID NO: 2 cannot be used to produce host cells comprising the nucleic acid encoding SEQ ID NO: 2. Since it is not predictable as to what proteins are encoded by the complements, it is not predictable as to what proteins can be detected by the antibodies generated by the polypeptides encoded by the complements. As discussed above, neither the specification nor the prior art provides guidance as to what polypeptides are encoded by the complement of a nucleic acid encoding a G-protein coupled receptor. Additionally, it is pointed out that the use of a polypeptide to generate antibodies to detect itself does not satisfy the statute's requirement of providing a disclosure that adequately teaches the skilled artisan to make and/or use the claimed invention.

It is not clear from page 10 of applicant's response as to what are redundant sequences. Nevertheless, it is reiterated that claims directed to the polynucleotides encoding SEQ ID NO: 2 are enabled by the specification. In fact, claims comprising polynucleotides that have 95%

sequence identity with the nucleic acid encoding SEQ ID NO: 2 are enabled by the specification. Thus, applicant's arguments on pages 11 to the top of 14 are deemed to be moot.

Applicant contends that the polypeptides encoded by the polynucleotides having 95% sequence identity to the polynucleotide encoding SEQ ID NO: 2 can be used to generate antibodies for detecting themselves and for use in the production of host cells comprising the respective polynucleotides. As discussed above, the specification does not teach how to use antibodies in the production of host cells comprising a specific polynucleotide. Also, as explained under the § 112, first paragraph, rejection, it is not predictable as to what polypeptides are encoded by polynucleotides having 95% sequence identity with the nucleic acid encoding SEQ ID NO: 2. It is not predictable that such a polypeptide is a G-protein coupled receptor because amino acid alterations affect the functional activity of a polypeptide. Even if the polypeptides encoded by the polynucleotides having 95% sequence identity can generate antibodies, it is not predictable as to what polypeptides such antibodies can detect.

Applicant contends that the only issue with respect to the claimed invention is the issue of utility for the polypeptides produced. However, it is pointed out that the present rejection is under § 112, first paragraph, not § 101. The issue at hand is whether the specification provides a disclosure that enables the skilled artisan to make and/or use the claimed invention. As discussed above, the specification does not enable the skilled artisan to practice the claimed invention of claims 31-33.

6. Claims 21-30 and 34-41 are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sally Teng, Ph.D., whose telephone number is (703) 308-4230. The examiner can normally be reached on Mon.-Fri. from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stephen Walsh, can be reached on (703) 308-2957.

Official papers filed by fax should be directed to (703) 305-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [**stephen.walsh@uspto.gov**].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SALLY TENG
PATENT EXAMINER
GROUP 1800